

RemarksIntroduction

Claims 63-74, 76, 77, 79-89, 91, 92, 94-108, 110 and 111 are pending. The claim rejections set forth in the Final Office Action mailed December 29, 2005 are addressed below. In addition, a new declaration under 37 C.F.R. § 131 is attached. Applicants have arranged the discussion such that all rejections relating to each of the three sets of claims are grouped together.

Claim Rejections Relating to Independent Claim 63 and Claims Dependent Thereon

A. Claims 63-65, 67-69, 76 and 77 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,155,019 to Sussman ("Sussman"), in view of U.S. Patent No. 3,831,030 to Wrobel et al. ("Wrobel") or U.S. Patent No. 4,857,735 to Noller ("Noller") or U.S. Patent No. 6,639,678 to Veale ("Veale"), taken further in view of U.S. Patent No. 4,073,691 to Ahnell et al. ("Ahnell") and U.S. Patent No. 4,730,112 ("Wong"). The rejection is respectfully traversed.

Claim 63, on which all the other rejected claims depend, recites a system comprising:

- a plurality of containers; and
- an apparatus, the apparatus comprising:
 - a module comprising a plurality of openings configured for receiving said containers;
 - a laser that emits, through at least one of said containers, radiation at a substantially single wavelength at which O₂ gas absorbs radiation;
 - a detector that detects at least a portion of said radiation that passes through said container; and
 - a signal analyzer that analyzes said detected radiation, wherein the signal analyzer determines at least one parameter selected from the group consisting of the pressure in the container, the existence of O₂ gas in the container, and the concentration of O₂ gas in the container.

Applicants position is that there would have been no motivation to combine the references in the manner asserted by the Examiner. Moreover, even if combined, the teachings are so disparate that it is not apparent what one skilled in the art would have done with the combination, particularly given the lack of focus on oxygen in the majority of the references.

Sussman: Sussman discloses use of an FT-IR technique to monitor CO₂ presence in a container. Oxygen is not mentioned. Sussman only states "other metabolically formed gases may be detected, provided an infrared absorption band exists for the compound and provided that the container material has a region of infrared transmittance of at least $\pm 10 \text{ CM}^{-1}$ at the absorption wavelength of the gaseous product with at least about 1 percent transmission at the wavelength region of interest." (Col. 6, lines 27-34.) This section of Sussman would indicate to a reader that other gases could be detected only if they meet a set of detection criteria. Sussman thus does not enable detection of such other gases, but merely suggests it might be possible.

Wrobel: Wrobel discloses use of a diode laser, operable in the 2 to 6 micrometer range, to do spectroscopic analysis of gases and vapors. (Applicants note that claim 65 recites that the emission wavelength is 761.5 nm, outside the range of Wrobel.)

Noller: Noller discloses use of a laser to detect components of liquid, not gas samples, by spectrophotometry. Moreover, Noller states that it considers the infrared region to be 0.94 micrometers (Col. 3, lines 30-31.).

Veale: Veale is relied on by the Examiner solely for its teaching of using tunable diode lasers for spectroscopy with sample containers. Applicants note that Veale was filed July 13, 2000. As shown by the attached Declaration under 37 C.F.R. § 1.131 (different from the previously-submitted declaration), applicants had conceived and reduced to practice use of a tunable laser for spectroscopy of gas samples in containers before this filing date. For this reason, Veale cannot be cited as prior art under §102(e). Applicants believe the attached declaration addresses the objections made to the previously-submitted declaration (see paragraph 17 of the Final Office Action).

Ahnell: Ahnell discloses detection of CO₂ from a sample to be tested for biological activity. Ahnell's preferred method is mass spectrometry, with listed alternatives including gas chromatography, catalytic testing, sulfur specific flame photometric detection, electron capture detection, infrared absorption, thermal-conductivity, dielectric constant, and sound velocity. (Col. 6, line 24 to Col. 7, line 5.) Moreover, Ahnell discloses that all these techniques require the sample to be removed

from a container, and then transferred to the selected test apparatus. Ahnell discloses that if one wishes to test the gas within the culture vial itself, one can insert a probe into the vial through a septum. (Col. 7, lines 6-18.) Applicants note the Examiner's reliance on a statement in Ahnell that a variety of gases might be of interest.

Wong: Wong is discussed above. Applicants note that Wong does not disclose a container, and discloses a laser that emits at multiple wavelengths.

Applicants submit that the disparate nature of these references is apparent from the above summaries, and that the requisite motivation to combine them in the asserted manner is therefore lacking.

The lack of motivation to combine is even more apparent by analyzing what the combination would suggest to one skilled in the art. For example, given that: Sussman teaches FT-IR to find CO₂ gas; Wrobel teaches use of a diode laser to detect gases in a wavelength range outside that of interest for oxygen; Noller discloses detection of components from a liquid, and discloses an IR range different from the IR range of Sussman and Wrobel; Ahnell focuses on detection techniques far different from those of the other references, some of which require removal of a gaseous sample; and Wong is silent on use of containers and teaches scanning through multiple wavelengths, applicants submit that one skilled in the art would be at a loss when trying to decide what this combination suggests one should actually make. What is clear is that the combination does not, without some hindsight-based picking and choosing, lead to applicants' claim 63. Applicants note in particular claim 65, which recites the particular wavelength of approximately 761.5 nanometers. The references clearly do not direct one skilled in the art to this specific wavelength. Wong does mention three O₂ bands – 760nm, 1.07um, 1.27um. However, these are specific wavelengths and would not lead to 761.5nm.

For these reasons, applicants submit that claim 63, and the claims dependent thereon, are not rendered obvious by the cited references.

B. Claim 66 was rejected under §103(a) as being unpatentable over Sussman, in view of Wrobel or Noller or Veale, taken further in view of Ahnell and Wong, and taken further in view of U.S. Patent No. 4,952,498 to Waters ("Waters") and U.S. Patent No. 5,614,718 to Brace ("Brace"). The rejection is respectfully traversed.

Claim 66 recites that the signal analyzer of claim 63 determines pressure in the container.

Waters discloses a culture vessel having an expandable membrane, which expands upon increased pressure in the vial. The membrane can be used to indicate growth of microorganisms.

Brace discloses that IR spectrometry measurements can be correlated with CO₂ pressure in a container.

Neither reference remedies the shortcomings of the primary and secondary references as discussed above with respect to claim 63, i.e., neither reference suggests that one skilled in the art should combine the primary and secondary references in the manner required to reach the claimed invention. Further, applicants note (1) that Waters does not involve any type of spectrometry, and (2) that claim 63 relates to oxygen whereas Brace focuses on CO₂ while simply mentioning that other gases may work as well.

For these reasons, and those above, applicants submit that dependent claim 66 is patentable over the cited references.

C. Claims 70-72 were rejected under §103(a) as being unpatentable over Sussman, in view of Wrobel or Noller or Veale, taken further in view of Ahnell and Wong, and taken further in view of U.S. Patent No. 5,888,825 to Carr et al. ("Carr"). The rejection is respectfully traversed.

Claim 70 recites that the system of claim 63 further comprises a housing, adapted to house said laser and said detector, where the housing is movable such that said laser and said detector are capable of being located proximate to each of said containers, sequentially in time. Claim 71 recites that the containers are arranged in a plurality of rows and columns, and the housing is adapted to move along said rows and said columns. Claim 72 recites that the housing is adapted to extend said laser and said detector toward each said container and to retract said laser and said detector away from each said container.

Carr is alleged to make the configurations of claims 70 to 72 obvious. Carr discloses an apparatus for housing an array of items, such as culture vessels. A sensor is provided, capable of moving in the x and y directions through the array, to gather information on the individual items.

Carr does not remedy the shortcomings of the primary and secondary references as discussed above, with respect to independent claim 63, i.e., the reference does not suggest that one skilled in the art should combine the primary and secondary references in the manner required to reach the claimed invention. In fact, Carr complicates the asserted combination. Specifically, Carr does not disclose a spectrometry technique utilizing a laser and detector to monitor absorption by a particular gas, but instead focuses on a pressure-monitoring technique in which a diaphragm is monitored (e.g., of the type disclosed in Waters). In addition, Carr is silent on a housing of the type recited in claim 72.

For these reasons, and those above, applicants submit claims 70-72 are patentable over the cited references.

D. Claims 73 and 74 were rejected under §103(a) as being unpatentable over Sussman, in view of Wrobel or Noller or Veale, taken further in view of Ahnell and Wong, and taken further in view of U.S. Patent No. 5,518,923 to Berndt et al. ("Berndt"). The rejection is respectfully traversed.

Claim 73 recites that the system comprises a housing having a plurality of openings therein, each said opening adapted to receive one of said containers, and wherein the housing is movable such that each of said containers is capable of being moved proximate to said laser and said detector. Claim 74 recites that the housing is substantially circular, wherein said openings are disposed circumferentially about said housing, and wherein said housing rotates to move said containers proximate to said laser and said detector.

Berndt does not remedy the shortcomings of the primary and secondary references as discussed above, with respect to independent claim 63, i.e., the reference does not suggest that one skilled in the art should combine the primary and secondary references in the manner required to reach the claimed invention. In fact, Berndt complicates the asserted combination. Specifically, Berndt discloses a more conventional fluorescence technique, not a spectrometry technique utilizing a laser and detector to monitor absorption by a particular gas.

For these reasons, and those above, applicants submit claims 73 and 74 are patentable over the cited references.

Claim Rejections Relating to Independent Claim 79 and Claims Dependent Thereon

A. Claims 79, 80, 82-84, 91 and 92 were rejected under §103(a) as being unpatentable over Sussman, in view of Wrobel or Noller or Veale, taken further in view of U.S. Patent No. 5,473,161 to Nix et al. ("Nix"). The rejection is respectfully traversed.

Applicants position is that there would have been no motivation to combine the references in the manner asserted by the Examiner. Moreover, even if combined, the teachings are so disparate that it is not apparent what one skilled in the art would have done with the combination.

Sussman: Sussman discloses use of an FT-IR technique to monitor CO₂ presence in a container. The reference discloses that the wavelengths of interest for CO₂ are 2400CM⁻¹ to 2300CM⁻¹ (i.e., 1/2400 to 1/2300 centimeters), which converts to a range of 4.35 to 4.17 micrometers (Col. 4, line 36). In fact, Sussman focuses on the

fact that polymethylpentene containers have a window of transparency at 2349CM^{-1} (which converts to 4.26 micrometers) (Col. 4, lines 61-62).

Wrobel: Wrobel discloses use of a diode laser, operable in the 2 to 6 micrometer range. For analysis of CO_2 , Wrobel teaches use of its laser at a wavelength of 4.28 micrometer (Col. 3, line 7).

Noller: Noller discloses use of a laser to detect components of liquid, not gas, by spectrophotometry. Moreover, Noller states that it considers the infrared region to be 0.94 micrometers (Col. 3, lines 30-31.).

Veale: As noted above, Veale is not applicable prior art.

Nix: Nix discloses a conventional IR spectroscopy technique, such as discussed in Sussman, where a broad IR beam is directed through a container, and a specified wavelength of wavenumber 4922 to 5034 is detected. (See Col. 1, line 64 to Col. 2, line 4.)

Applicants submit that the disparate nature of these references is apparent from the above summaries, and that the requisite motivation to combine them in the asserted manner is therefore lacking. For example, of the four applicable references, two suggest a laser, and two suggest more conventional IR spectroscopy. Two suggest one particular wavelength for CO_2 detection while a third suggests a different wavelength, and a fourth suggests yet another IR wavelength.

Moreover, even if combined, the references would not lead one skilled in the art to the invention of claim 79. The disparate nature of the references in fact makes it unclear what one skilled in the art would do with the combination. Together, Sussman and Wrobel would have led one skilled in the art to use a wavelength around 4.26 to 4.28 micrometers, in order to analyze for the presence of CO_2 . Nix may or may not have motivated one to try its wavelengths, but obvious to try is not sufficient to support an obviousness rejection. And it is unclear what affect Noller might have, as it suggests an IR range different from both Sussman/Wrobel and Nix.

For these reasons, applicants submit that claim 79 and the claims dependent thereon, are patentable over the asserted combination.

B. Claim 81 was rejected under §103(a) as being unpatentable over Sussman in view of Wrobel or Noller or Veale, taken further in view of Nix, and taken further in view of Waters and Brace. The rejection is respectfully traversed.

Claim 81 recites that the signal analyzer of claim 79 determines pressure in the container.

Waters discloses a culture vessel having an expandable membrane, which expands upon increased pressure in the vial. The membrane can be used to indicate growth of microorganisms.

Brace discloses that IR spectrometry measurements can be correlated with CO₂ pressure in a container.

Neither reference remedies the shortcomings of the primary and secondary references as discussed above with respect to claim 79, i.e., neither reference suggests that one skilled in the art should combine the primary and secondary references in the manner required to reach the claimed invention. Further, applicants note that Waters does not involve any type of spectrometry.

For these reasons, and those above, applicants submit that dependent claim 81 is patentable over the cited references.

C. Claims 85-87 were rejected under §103(a) as being unpatentable over Sussman in view of Wrobel or Noller or Veale, taken further in view of Nix and taken further in view of Carr. The rejection is respectfully traversed.

Claim 85 recites that the system of claim 79 further comprises a housing, adapted to house said laser and said detector, where the housing is movable such that said laser and said detector are capable of being located proximate to each of said containers, sequentially in time. Claim 86 recites that the containers are arranged in a plurality of rows and columns, and the housing is adapted to move along said rows and said columns. Claim 87 recites that the housing is adapted to extend said laser and said detector toward each said container and to retract said laser and said detector away from each said container.

Carr is alleged to make the configurations of claims 85 to 87 obvious. Carr discloses an apparatus for housing an array of items, such as culture vessels. A sensor is provided, capable of moving in the x and y directions through the array, to gather information on the individual items.

Carr does not remedy the shortcomings of the primary and secondary references as discussed above, with respect to independent claim 79, i.e., the reference does not suggest that one skilled in the art should combine the primary and secondary references in the manner required to reach the claimed invention. In fact, Carr complicates the asserted combination. Specifically, Carr does not disclose a spectrometry technique utilizing a laser and detector to monitor absorption by a particular gas, but instead focuses on a pressure-monitoring technique in which a diaphragm is monitored (e.g., of the type disclosed in Waters). In addition, Carr is silent on a housing of the type recited in claim 87.

For these reasons, and those above, applicants submit claims 85-87 are patentable over the cited references.

D. Claims 88 and 89 were rejected under §103(a) as being unpatentable over Sussman, in view of Wrobel or Noller or Veale, taken further in view of Ahnell and Wong, and taken further in view of U.S. Patent No. 5,518,923 to Berndt et al. ("Berndt"). The rejection is respectfully traversed.

Claim 88 recites that the system comprises a housing having a plurality of openings therein, each said opening adapted to receive one of said containers, and wherein the housing is movable such that each of said containers is capable of being moved proximate to said laser and said detector. Claim 89 recites that the housing is substantially circular, wherein said openings are disposed circumferentially about said housing, and wherein said housing rotates to move said containers proximate to said laser and said detector.

Berndt does not remedy the shortcomings of the primary and secondary references as discussed above, with respect to independent claim 79, i.e., the reference does not suggest that one skilled in the art should combine the primary and secondary references in the manner required to reach the claimed invention. In fact, Berndt complicates the asserted combination. Specifically, Berndt discloses a more conventional fluorescence technique, not a spectrometry technique utilizing a laser and detector to monitor absorption by a particular gas.

For these reasons, and those above, applicants submit claims 88 and 89 are patentable over the cited references.

Claim Rejections Relating to Independent Claim 94 and Claims Dependent Thereon

A. Claims 94-99, 101-103, 110 and 111 were rejected under §103(a) as being unpatentable over Sussman in view of Wrobel or Noller or Veale, taken further in view of Ahnell and Allen, "Diode Laser Absorption Sensors for Gas Dynamic and Combustion Flows," *Measurement Science and Technology*, 9(4), 545-562 (1998) ("Allen"). The rejection is respectfully traversed.

Claim 94, on which all the other rejected claims depend, recites a system comprising:

- a plurality of containers; and
- an apparatus, the apparatus comprising:

- a module comprising a plurality of openings configured for receiving said containers;
- a laser that emits, through at least one of said containers, radiation at a substantially single wavelength at which a gas selected from the group consisting of NH_3 , H_2S , CH_4 and SO_2 absorbs radiation;
- a detector that detects at least a portion of said radiation that passes through said container; and
- a signal analyzer that analyzes said detected radiation, wherein the signal analyzer determines at least one parameter selected from the group consisting of the pressure in the container, the existence of the gas in the container, and the concentration of the gas in the container.

Applicants position is that there would have been no motivation to combine the references in the manner asserted by the Examiner. Moreover, even if combined, the teachings are so disparate that it is not apparent what one skilled in the art would have done with the combination, particularly given the lack of focus on the recited gases in the references.

Sussman: Sussman discloses use of an FT-IR technique to monitor CO_2 presence in a container. The recited gases are not mentioned. Sussman only states "other metabolically formed gases may be detected, provided an infrared absorption band exists for the compound and provided that the container material has a region of infrared transmittance of at least $\pm 10 \text{ CM}^{-1}$ at the absorption wavelength of the gaseous product with at least about 1 percent transmission at the wavelength region of interest." (Col. 6, lines 27-34.) This section of Sussman would indicate to a reader that other gases could be detected only if they meet a set of detection criteria. Sussman thus does not enable detection of such other gases, but merely suggests it might be possible.

Wrobel: Wrobel discloses use of a diode laser, operable in the 2 to 6 micrometer range, to do spectroscopic analysis of gases and vapors.

Noller: Noller discloses use of a laser to detect components of liquid, not gas, by spectrophotometry.

Veale: As noted above, Veale is not applicable prior art.

Ahnell: Ahnell discloses detection of CO_2 from a sample to be tested for biological activity. Ahnell's preferred method is mass spectrometry, with listed alternatives including gas chromatography, catalytic testing, sulfur specific flame photometric detection, electron capture detection, infrared absorption, thermal-

conductivity, dielectric constant, and sound velocity. (Col. 6, line 24 to Col. 7, line 5.) Moreover, Ahnell discloses that all these techniques require the sample to be removed from a container, and then transferred to the selected test apparatus. Ahnell discloses that if one wishes to test the gas within the culture vial itself, one can insert a probe into the vial through a septum. (Col. 7, lines 6-18.) Applicants note the Examiner's reliance on a statement in Ahnell that a variety of gases might be of interest.

Allen: Allen is directed to real-time monitoring of effluents, combustion gases, and gases in similar industrial applications. (Hence the title: "...gas dynamic and combustion flows.") See, e.g., the Abstract.

Applicants submit that the disparate nature of these references is apparent from the above summaries, and that the requisite motivation to combine them in the asserted manner is therefore lacking.

The lack of motivation to combine is even more apparent by analyzing what the combination would suggest to one skilled in the art. For example, given that: Sussman teaches FT-IR to find CO₂ gas; Wrobel teaches use of a diode laser to detect gases in a wavelength range outside that of interest for the recited gases; Noller discloses detection of components from a liquid, and discloses an IR range different from the IR range of Sussman and Wrobel; Ahnell focuses on detection techniques far different from those of the other references, some of which require removal of a gaseous sample; and Allen broadly discloses a variety of diode-based sensors for industrial applications, applicants submit that one skilled in the art would be at a loss when trying to decide what this combination suggests they actually make. What is clear is that the combination does not, without some hindsight-based picking and choosing, lead to applicants' claim 94, particularly because the primary references do not provide information or direction as to the recited gases. Applicants note in particular the wavelengths recited in claims 96-99.

For these reasons, applicants submit that claim 94, and the claims dependent thereon, are not rendered obvious by the cited references.

B. Claim 100 was rejected under §103(a) as being unpatentable over Sussman, in view of Wrobel or Noller or Veale, taken further in view of Ahnell and Allen and taken further in view of Waters and Brace. The rejection is respectfully traversed.

Claim 100 recites that the signal analyzer of claim 94 determines pressure in the container.

Waters discloses a culture vessel having an expandable membrane, which expands upon increased pressure in the vial. The membrane can be used to indicate growth of microorganisms.

Brace discloses that IR spectrometry measurements can be correlated with CO₂ pressure in a container.

Neither reference remedies the shortcomings of the primary and secondary references as discussed above with respect to claim 94, i.e., neither reference suggests that one skilled in the art should combine the primary and secondary references in the manner required to reach the claimed invention. Further, applicants note (1) that Waters does not involve any type of spectrometry, and (2) that claim 94 relates to the list of recited gases whereas Brace focuses on CO₂ while simply mentioning that other gases may work as well.

For these reasons, and those above, applicants submit that dependent claim 100 is patentable over the cited references.

C. Claims 104-106 were rejected under §103(a) as being unpatentable over Sussman, in view of Wrobel or Noller or Veale, taken further in view of Ahnell and Allen, and taken further in view of Carr. The rejection is respectfully traversed.

Claim 104 recites that the system of claim 94 further comprises a housing, adapted to house said laser and said detector, where the housing is movable such that said laser and said detector are capable of being located proximate to each of said containers, sequentially in time. Claim 105 recites that the containers are arranged in a plurality of rows and columns, and the housing is adapted to move along said rows and said columns. Claim 106 recites that the housing is adapted to extend said laser and said detector toward each said container and to retract said laser and said detector away from each said container.

Carr is alleged to make the configurations of claims 104 to 106 obvious. Carr discloses an apparatus for housing an array of items, such as culture vessels. A sensor is provided, capable of moving in the x and y directions through the array, to gather information on the individual items.

Carr does not remedy the shortcomings of the primary and secondary references as discussed above, with respect to independent claim 94, i.e., the reference does not suggest that one skilled in the art should combine the primary and secondary references in the manner required to reach the claimed invention. In fact, Carr complicates the asserted combination. Specifically, Carr does not disclose a spectrometry technique utilizing a laser and detector to monitor absorption by a particular gas, but instead focuses on a pressure-monitoring technique in which a

diaphragm is monitored (e.g., of the type disclosed in Waters). In addition, Carr is silent on a housing of the type recited in claim 106.

For these reasons, and those above, applicants submit claims 104-106 are patentable over the cited references.

D. Claims 107 and 108 were rejected under §103(a) as being unpatentable over Sussman, in view of Wrobel or Noller or Veale, taken further in view of Ahnell and Allen, and taken further in view of Berndt. The rejection is respectfully traversed.

Claim 107 recites that the system comprises a housing having a plurality of openings therein, each said opening adapted to receive one of said containers, and wherein the housing is movable such that each of said containers is capable of being moved proximate to said laser and said detector. Claim 108 recites that the housing is substantially circular, wherein said openings are disposed circumferentially about said housing, and wherein said housing rotates to move said containers proximate to said laser and said detector.

Berndt does not remedy the shortcomings of the primary and secondary references as discussed above, with respect to independent claim 94, i.e., the reference does not suggest that one skilled in the art should combine the primary and secondary references in the manner required to reach the claimed invention. In fact, Berndt complicates the asserted combination. Specifically, Berndt discloses a more conventional fluorescence technique, not a spectrometry technique utilizing a laser and detector to monitor absorption by a particular gas.

For these reasons, and those above, applicants submit claims 107 and 108 are patentable over the cited references.

For the reasons above, applicants submit that the claims are patentable over the cited references, and withdrawal of the rejections and allowance of all claims is respectfully requested.

If there are any additional fees related to this Amendment, such fees should be charged to Deposit Account No. 02-1666.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Scott J. Rittman", written in a cursive style.

Scott J. Rittman
Registration No. 39,010

BECTON, DICKINSON AND COMPANY
1 Becton Drive
Franklin Lakes, NJ 07417-1880
Scott_rittman@bd.com
Tel: (201) 847-6356
Fax: (201) 848-9228
Doc#107932